

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN  
DISTRICT OF MISSOURI, EASTERN DIVISION

LAURA PURICELLI, ROBERT )  
MERRICK and LISA CLOUSE, )  
 )  
Plaintiffs, )  
 )  
vs. )  
 )  
GENENTECH, INC., BIOGEN IDEC, )  
INC., )  
 )  
Defendants. )

Cause No: 4:10-CV-01793-JCH

**AMENDED COMPLAINT**

**COUNT I**

**WRONGFUL DEATH- STRICT LIABILITY**

COME NOW PLAINTIFFS, Laura Puricelli, Robert Merrick, and Lisa Clouse, children of Mary Merrick, deceased, by and through their attorneys, Holland, Groves, Schneller & Stolze, L.L.C., and for their cause of action for the wrongful death of Mary Merrick against Defendants, Genentech, Inc. and Biogen Idec Inc., states as follows:

1. Plaintiff Laura Puricelli is a resident of the State of Missouri and is the daughter of the decedent, Mary Merrick.
2. Plaintiff Robert Merrick is a resident of the State of Missouri and is the son of the decedent, Mary Merrick.
3. Plaintiff Lisa Clouse is a resident of the State of Missouri and is the daughter of the decedent, Mary Merrick.
4. Plaintiffs are proper parties to bring this action pursuant to 537.080 RSMo.
5. Defendant Genentech, Inc. (Genentech) is a Delaware corporation with its principal place of business in South San Francisco, California. Genentech is a biotechnology

company engaged in the development, manufacturing, commercialization, and marketing of various pharmaceutical products, including Rituximab a/k/a Rituxan.

6. At all relevant times herein, Genentech has conducted business activities, including the marketing and sale of Rituxan in the City of St. Louis, State of Missouri.

7. Defendant Biogen Idec, Inc. (Biogen) is a Delaware corporation with its principal place of business in Cambridge, Massachusetts. Biogen is a biotechnology company engaged in the development, manufacturing, commercialization, and marketing of various pharmaceutical products, including Rituximab a/k/a Rituxan.

8. At all relevant times herein, Defendant Biogen has conducted business activities, including the marketing and sale of Rituxan in the City of St. Louis, State of Missouri.

9. Decedent was first injured in the City of St. Louis, State of Missouri.

10. Defendants Genentech and Biogen jointly developed Rituxan.

11. Defendant Genentech licenses Rituxan from Defendant Biogen.

12. At all relevant times herein, Defendant Genentech had a sales and marketing staff dedicated to sales and promotion of Rituxan.

13. At all relevant times herein, Defendant Biogen had a sales and marketing staff dedicated to sales and promotion of Rituxan.

14. Defendants Genentech and Biogen market and sell Rituxan in collaboration with one another and have ratified the acts of each other described in this petition and formulated, manufactured, distributed and sold Rituxan.

15. Rituxin should not be used except in adult patients with moderate to severely active rheumatoid arthritis (RA) who have inadequately responded to one or more prior tumor necrosis factor (TNF) antagonist therapies.

16. Rituxan was first administered to Decedent in or about February, 2009 in the City of St. Louis.

17. Decedent Mary Merrick had never received a prior TNF antagonist therapy course at the time Rituxan was prescribed. Therefore, the prescription was “off-label” as it had not been approved for such usage.

18. Defendants marketed Rituxan as safe and effective for the treatment of various diseases including those for which its use would be “off-label”.

19. Defendants knew or should have known that the use of Rituxan presented risk of extremely serious injury or death. Patients who had received Rituxan suffered from profound immunosuppression that led to serious and untreatable illnesses such as community viral infections or progressive multifocal leukoencephalopathy (PML).

20. That due to the failure of defendants to adequately warn of the risks of the use of Rituxan Decedent did not know of the risks she was exposed to that ultimately led to her death.

21. On October 21, 2009, Mary Merrick died as a result of PML.

22. Defendants Biogen Idec, Inc. and Genentech, Inc. are engaged in the business of manufacturing, marketing, and selling pharmaceutical drugs for distribution and human use throughout the United States, and in particular to this action, St. Louis, Missouri.

23. Decedent, Mary Merrick, was given a warning pamphlet with a prescription of Rituxan, manufactured and/or marketed and/or sold by Defendants, which failed to adequately warn of the increased risk of the potentially fatal side effects such as PML which may occur when Rituxan is administered.

24. Because of this failure to warn, the Rituxan taken by Decedent was defective and unreasonably dangerous when it left the custody and control of Defendants.

25. The deceased, Mary Merrick, used Defendants' Rituxan in a fashion that was reasonably anticipated by Defendants.

26. As a direct and proximate result of Defendants placing a defective product into the stream of commerce, the deceased, Mary Merrick, was caused to suffer terrible pain and suffering of the mind and body as a result of acquiring PML and was forced to undergo painful testing and diagnostic treatments, and ultimately died from PML. In addition, plaintiffs suffered loss of the care, comfort and consortium of their mother.

27. If defendants had provided an adequate warning it would have changed decedent's and/or her doctor's use of Rituxan.

28. That Rituxan has developed, manufactured, sold, marketed and administered was in a defective and unreasonably dangerous condition given the likelihood of severe injury or death from its use.

29. Plaintiffs further allege that the actions of Defendants were willful, wanton and done with a conscious disregard for the safety of the decedent, Mary Merrick, and those like her and therefore constitute aggravating factors supporting the entry of punitive damages against Defendants.

WHEREFORE, Plaintiffs, children of the deceased, Mary Merrick, pray for judgment against Defendants Genentech, Inc. and Biogen Idec, Inc. jointly and severally, and for a sum that is fair and reasonable under the circumstances which sum exceeds the jurisdictional amount, together with punitive damages and their costs herein.

COUNT II

WRONGFUL DEATH - NEGLIGENCE

COMES NOW, Laura Puricelli, Robert Merrick, and Lisa Clouse, children of Mary Merrick, deceased, by and through their attorneys, Holland, Groves, Schneller & Stolze, L.L.C., and for their cause of action for the wrongful death of Mary Merrick against Defendants, Genentech, Inc. and Biogen Idec Inc., states as follows:

30. Plaintiff Laura Puricelli is a resident of the State of Missouri and is the daughter of the decedent, Mary Merrick.

31. Plaintiff Robert Merrick is a resident of the State of Missouri and is the son of the decedent, Mary Merrick.

32. Plaintiff Lisa Clouse is a resident of the State of Missouri and is the daughter of the decedent, Mary Merrick.

33. Plaintiffs are proper parties to bring this action pursuant to 537.080 R.S.Mo.

34. Defendant Genentech, Inc. (Genentech) is a Delaware corporation with its principal place of business in South San Francisco, California. Genentech is a biotechnology company engaged in the development, manufacturing, commercialization, and marketing of various pharmaceutical products, including Rituximab a/k/a Rituxan.

35. At all relevant times herein, Genentech has conducted business activities, including the marketing and sale of Rituxan in the City of St. Louis, State of Missouri.

36. Defendant Biogen Idec, Inc. (Biogen) is a Delaware corporation with its principal place of business in Cambridge, Massachusetts. Biogen is a biotechnology company engaged in the development, manufacturing, commercialization, and marketing of various pharmaceutical products, including Rituximab a/k/a Rituxan.

37. At all relevant times herein, Defendant Biogen has conducted business activities, including the marketing and sale of Rituxan in the City of St. Louis, State of Missouri.

38. Decedent was first injured in the City of St. Louis, State of Missouri.

39. Defendants Genentech and Biogen jointly developed Rituxan.

40. Defendant Genentech licenses Rituxan from Defendant Biogen.

41. At all relevant times herein, Defendant Genentech had a sales and marketing staff dedicated to sales and promotion of Rituxan.

42. At all relevant times herein, Defendant Biogen had a sales and marketing staff dedicated to sales and promotion of Rituxan.

43. Defendants Genentech and Biogen market and sell Rituxan in collaboration with one another and have ratified the acts of each other described in this petition and formulated, manufactured, distributed and sold Rituxan.

44. Rituxin should not be used except in adult patients with moderate to severely active rheumatoid arthritis (RA) who have inadequately responded to one or more prior tumor necrosis factor (TNF) antagonist therapies.

45. Rituxan was first administered to Decedent in or about February, 2009 in the City of St. Louis.

46. Decedent Mary Merrick had never received a prior TNF antagonist therapy course at the time Rituxan was prescribed. Therefore, the prescription was “off-label” as it had not been approved for such usage.

47. Defendants marketed Rituxan as safe and effective for the treatment of various diseases including those for which its use would be “off-label”.

48. Defendants knew or should have known that the use of Rituxan presented risk of extremely serious injury or death. Patients who had received Rituxan suffered from profound immunosuppression that led to serious and untreatable illnesses such as community viral infections or progressive multifocal leukoencephalopathy (PML).

49. That due to the failure of defendants to adequately warn of the risks of the use of Rituxan Decedent did not know of the risks she was exposed to that ultimately led to her death.

50. On October 21, 2009, Mary Merrick died as a result of PML.

51. Defendants Biogen Idec, Inc. and Genentech, Inc. are engaged in the business of manufacturing, marketing, and selling pharmaceutical drugs for distribution and human use throughout the United States, and in particular to this action, St. Louis, Missouri.

52. Decedent, Mary Merrick, was given a warning pamphlet with a prescription of Rituxan, manufactured and/or marketed and/or sold by Defendants, which failed to adequately warn of the increased risk of the potentially fatal side effects such as PML which may occur when Rituxan is administered.

53. Because of this failure to warn, the Rituxan taken by Decedent was unreasonably dangerous when it left the custody and control of Defendants.

54. The deceased, Mary Merrick, used Defendants' Rituxan in a fashion that was reasonably anticipated by Defendants.

55. Defendants knew or should have known that the deceased, Mary Merrick, would not realize the increased dangers posed by Rituxan.

56. Defendants knew or should have known of the dangerous condition of the product caused by its defective warning.

57. As a direct and proximate result of Defendants negligent placement of an unsafe product into the stream of commerce, the deceased, Mary Merrick, was caused to suffer terrible pain and suffering of the mind and body as a result of acquiring PML and was forced to undergo painful testing and diagnostic treatments, and ultimately died from PML. In addition, plaintiffs suffered loss of the care, comfort and consortium of their mother.

58. If defendants had provided an adequate warning it would have changed decedent's and/or her doctor's use of Rituxan.

59. Rituxan was not reasonably safe as formulated, marketed, distributed, administered and used by defendants.

60. Plaintiffs further allege that the actions of Defendants were willful, wanton and done with a conscious disregard for the safety of the decedent, Mary Merrick, and those like her and therefore constitute aggravating factors supporting the entry of punitive damages against Defendants.

WHEREFORE, Plaintiffs, children of the deceased, Mary Merrick, pray for judgment against Defendants Genentech, Inc. and Biogen Idec, Inc. jointly and severally, and for a sum that is fair and reasonable under the circumstances which sum exceeds the jurisdictional amount, together with punitive damages and their costs herein.



COUNT III

WRONGFUL DEATH & NEGLIGENT MISREPRESENTATION

COMES NOW, Laura Puricelli, Robert Merrick, and Lisa Clouse, children of Mary Merrick, deceased, by and through their attorneys, Holland, Groves, Schneller & Stolze, L.L.C., and for their cause of action for the wrongful death of Mary Merrick against Defendants, Genentech, Inc. and Biogen Idec Inc., states as follows:

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62. Plaintiff Robert Merrick is a resident of the State of Missouri and is the son of the decedent, Mary Merrick.

63. Plaintiff Lisa Clouse is a resident of the State of Missouri and is the daughter of the decedent, Mary Merrick.

64. Plaintiffs are proper parties to bring this action pursuant to 537.080 R.S.Mo.

65. Defendant Genentech, Inc. (Genentech) is a Delaware corporation with its principal place of business in South San Francisco, California. Genentech is a biotechnology company engaged in the development, manufacturing, commercialization, and marketing of various pharmaceutical products, including Rituximab a/k/a Rituxan.

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68. At all relevant times herein, Defendant Biogen has conducted business activities, including the marketing and sale of Rituxan in the City of St. Louis, State of Missouri.

69. Decedent was first injured in the City of St. Louis, State of Missouri.

70. Defendants Genentech and Biogen jointly developed Rituxan.

71. Defendant Genentech licenses Rituxan from Defendant Biogen.

72. At all relevant times herein, Defendant Genentech had a sales and marketing staff dedicated to sales and promotion of Rituxan.

73. At all relevant times herein, Defendant Biogen had a sales and marketing staff dedicated to sales and promotion of Rituxan.

74. Defendants Genentech and Biogen market and sell Rituxan in collaboration with one another and have ratified the acts of each other described in this petition and formulated, manufactured, distributed and sold Rituxan.

75. Rituxin should not be used except in adult patients with moderate to severely active rheumatoid arthritis (RA) who have inadequately responded to one or more prior tumor necrosis factor (TNF) antagonist therapies.

76. Rituxan was first administered to Decedent in or about February, 2009 in the City of St. Louis.

77. Decedent Mary Merrick had never received a prior TNF antagonist therapy course at the time Rituxan was prescribed. Therefore, the prescription was “off-label” as it had not been approved for such usage.

78. Defendants marketed Rituxan as safe and effective for the treatment of various diseases including those for which its use would be “off-label”.

79. Defendants knew or should have known that the use of Rituxan presented risk of extremely serious injury or death. Patients who had received Rituxan suffered from profound immunosuppression that led to serious and untreatable illnesses such as community viral infections or progressive multifocal leukoencephalopathy (PML).

80. That due to the failure of defendants to adequately warn of the risks of the use of Rituxan Decedent did not know of the risks she was exposed to that ultimately led to her death.

81. On October 21, 2009, Mary Merrick died as a result of PML.

82. Defendants Biogen Idec, Inc. and Genentech, Inc. are engaged in the business of manufacturing, marketing, and selling pharmaceutical drugs for distribution and human use throughout the United States, and in particular to this action, St. Louis, Missouri.

83. Decedent, Mary Merrick, was given a warning pamphlet with a prescription of Rituxan, manufactured and/or marketed and/or sold by Defendants, which failed to adequately warn of the increased risk of the potentially fatal side effects such as PML which may occur when Rituxan is administered.

84. Defendants intended that decedent, Mary Merrick, would rely on the information in the warning pamphlet in weighing the risks associated with Rituxan and deciding whether to take the drug.

85. The representations that Defendants made in their warning pamphlet were material to the decedent, Mary Merrick's, decision to take Rituxan.

86. Before and at the time decedent, Mary Merrick, was prescribed Rituxan Defendants knew or should have known of the risk that Rituxan could trigger PML and would therefore be dangerous and contraindicated.

87. Defendants failed to exercise reasonable care in preparing the warning pamphlet.

88. Because Defendants knew or should have known of the risk that Rituxan could trigger PML and thus was not proper for use in persons who had not had an inadequate response to a prior TNF antagonist therapy and defendants failed to include such material information in the warning pamphlet, the representations made therein about the risks associated with Rituxan were false.

89. Decedent, Mary Merrick, relied on the representations that Defendants made in the warning pamphlet in her decision to take Rituxan and such reliance was reasonable under the circumstances.

90. Because of this failure to warn, the Rituxan taken by Decedent was defective and unreasonably dangerous when it left the custody and control of Defendants.

91. The deceased, Mary Merrick, used Defendants' Rituxan in a fashion that was reasonably anticipated by Defendants.

92. Defendants knew or should have known that the deceased, Mary Merrick, would not realize the increased dangers posed by Rituxan.

93. Defendants knew or should have known of the dangerous condition of the product caused by its defective warning.

94. As a direct and proximate result of Defendants negligent placement of an unsafe product into the stream of commerce, the deceased, Mary Merrick, was caused to suffer terrible pain and suffering of the mind and body as a result of acquiring PML and was forced to undergo painful testing and diagnostic treatments, and ultimately died from PML.

95. If defendants had provided an adequate warning it would have changed decedent's and/or her doctor's use of Rituxan.

96. Plaintiffs further allege that the actions of Defendants were willful, wanton and done with a conscious disregard for the safety of the decedent, Mary Merrick, and those like her and therefore constitute aggravating factors supporting the entry of punitive damages against Defendants.

WHEREFORE, Plaintiffs, children of the deceased, Mary Merrick, pray for judgment against Defendants Genentech, Inc. and Biogen Idec, Inc. jointly and severally, and for a sum that is fair and reasonable under the circumstances which sum exceeds the jurisdictional amount, together with punitive damages and their costs herein.

Respectfully submitted,

HOLLAND, GROVES, SCHNELLER  
& STOLZE, LLC

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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that the foregoing pleading was served this 3<sup>rd</sup> day of May, 2011, by the court's electronic filing system to:

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